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	ROANE, AARON F		
155 SEAPORT BOULEVARD	APER NUMBER		
BOSTON, MA 02210-2604 3739			

DATE MAILED: 01/26/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

		Applicati	nN.	Applicant(s)	- /D		
Office Action Summary		10/027,134		WELLMAN ET AL.			
		Examin r					
		Aaron Ro		3739			
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Period fo	• •	N V IO OET T	O EVOIDE « MONTH	(C) FDOM			
THE - Exte after - If the - If NC - Failu Any	ORTENED STATUTORY PERIOD FOR REF MAILING DATE OF THIS COMMUNICATION asions of time may be available under the provisions of 37 CFR SIX (6) MONTHS from the mailing date of this communication. period for reply specified above is less than thirty (30) days, a reperiod for reply is specified above, the maximum statutory period for reply within the set or extended period for reply will, by state reply received by the Office later than three months after the mailed patent term adjustment. See 37 CFR 1.704(b).	1.136(a). In no eve eply within the state of will apply and wi ute, cause the app	ent, however, may a reply be tir story minimum of thirty (30) day Il expire SIX (6) MONTHS from ication to become ABANDONE	nely filed s will be considered timely. the mailing date of this commu	unication.		
Status							
1)⊠	Responsive to communication(s) filed on <u>07 January 2005</u> .						
2a)□	This action is <b>FINAL</b> . 2b)⊠ Th	This action is non-final.					
3)	3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213.						
Disposit	ion of Claims						
4)⊠ 5)□ 6)⊠ 7)□	Claim(s) 1-4,6-13,15 and 16 is/are pending in the application.  4a) Of the above claim(s) is/are withdrawn from consideration.  Claim(s) is/are allowed.  Claim(s) 1-4,6-13,15 and 16 is/are rejected.  Claim(s) is/are objected to.  Claim(s) are subject to restriction and/or election requirement.						
Applicat	ion Papers						
9)	The specification is objected to by the Exami	ner.					
10)☐ The drawing(s) filed on is/are: a)☐ accepted or b)☐ objected to by the Examiner.							
	Applicant may not request that any objection to the	ne drawing(s) b	e held in abeyance. Se	e 37 CFR 1.85(a).			
11)	Replacement drawing sheet(s) including the correct The oath or declaration is objected to by the						
Priority (	under 35 U.S.C. § 119		•				
a)	Acknowledgment is made of a claim for foreign All b) Some * c) None of:  1. Certified copies of the priority docume as Copies of the priority docume application from the International Bure See the attached detailed Office action for a light	ents have bee ents have bee riority docum eau (PCT Rul	n received. n received in Applicat ents have been receiv e 17.2(a)).	ion No ed in this National Sta	ige		
Attachmer	it(s)						
1) Notice	ce of References Cited (PTO-892)		4) Interview Summary				
3) Infor	ce of Draftsperson's Patent Drawing Review (PTO-948) mation Disclosure Statement(s) (PTO-1449 or PTO/SB/0 er No(s)/Mail Date	08)	Paper No(s)/Mail D 5) Notice of Informal I 6) Other:	ate Patent Application (PTO-15	2)		

## **DETAILED ACTION**

## Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-4, 7, 8, 10, 13 and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yamanashi et al. (USPN 5,964,759) in view of Dorn (USPN 6,334,860 B1) in further view of Tetzlaff et al. (USPN 6,277,117 B1).

Regarding claims 1, 2, 7 and 13, Yamanashi et al. disclose a bipolar forceps device having a sharp pointed tissue-piercing distal tip, first and second members having non-destructive tissue-contacting conductive surfaces (tissue grasping surfaces of the jaw members (40 and 38)), wherein the first and second members are pivotably movable with respect to each other and connected to a power source, see col. 2-5 and figures 2, 3 and especially 4. Yamanashi et al. fail to explicitly show the pivot connected the first and second members and do not show a close up of the first and second conductive elements connected to the first and second members respectively. Additionally, Yamanashi et al.

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fail to disclose that the first and second tissue contacting conductive elements are substantially circular in shape extending along the length thereof. It is well known in the art to provide the first and second members disclosed by Yamanashi et al. with a pivotable connection in order to facilitate the opening and closing of the members with respect to each other and to place a first electrically conductive element on the first member and a second electrically conductive element on the second member in order to provide the bipolar electrosurgical forceps with grasping coagulating tissue grasping surfaces. As an illustrative example, Dorn discloses an electrosurgical forceps device and teach providing a pivot pin (72) between the first (16) and second (14) members in order to provide the members with opening and closing capabilities with respect to each other and also teach placing a first electrically conductive element (38) on the first member and a second electrically conductive element (36) on the second member in order to provide the bipolar electrosurgical forceps with grasping coagulating tissue grasping surfaces, see col. 4-7 and figures 1-3. Also it is well known in the art to provide forceps jaws with substantially circular shape extending along the length of the jaws, or curved jaws in order to provide the necessary sealing along a particular desired path. Tetzlaff et al. disclose an electrosurgical forceps device and teach the provision of curved forceps jaws (110 and 120) in order to provide hemostasis along a desired non-linear path, see col. 1-10 and figures 1-3. Therefore at the time of the invention it would have been obvious to one of ordinary skill in the art to modify the invention of Yamanashi et al., as is well known in the art and taught by Dorn, to provide a pivot pin between the first and second members in order to provide the members with opening and closing capabilities with

respect to each other and also teach placing a first electrically conductive element on the first member and a second electrically conductive element on the second member in order to provide the bipolar electrosurgical forceps with grasping coagulating tissue grasping surfaces, and as is well known in the art and further disclosed by Tetzlaff et al., to provide curved forceps jaws in order to provide hemostasis along a desired non-linear path.

Regarding claims 3 and 15, Yamanashi et al. in view of Dorn disclose an actuating member (loop rings of handle) mated to the first and second members and effective to selectively move the members between the open and closed positions, see figure 4 of Yamanashi et al.

Regarding claim 4, Yamanashi et al. in view of Dorn further that first and second members are elongate and each member includes a proximal end mated to the actuating member, and a distal portion having the conductive element disposed thereon.

Regarding claim 8, Yamanashi et al. in view of Dorn further that one of the first and second conductive elements is an active energy transmitting electrode, and the other one of the first and second conductive elements is a return electrode (this is inherent in a bipolar device).

Regarding claim 10, Yamanashi et al. in view of Dorn further disclose that an insulative coating (34 and 32) disposed around a portion of at least one of the first and second members, see Dorn figure 2 and col. 5.

Claims 6 and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yamanashi et al. (USPN 5,964,759) in view of Dorn (USPN 6,334,860 B1) in still further view of Tetzlaff et al. (USPN 6,277,117 B1) as applied to claim 1 above, and further in view of Nezhat et al. (USPN 6,514,252 B2).

Regarding claim 6, Yamanashi et al. in view of Dorn in still further view of Tetzlaff et al. disclose the claimed invention except for explicitly reciting that the first conductive element comprises first and second electrodes extending along the length of the distal portion of the first member and adapted to be positioned adjacent a tissue surface, and the second conductive element comprises a single electrode extending along the length of the distal portion of the second member and adapted to be positioned adjacent an opposed tissue surface between the first and second electrodes of the first member. Nezhat et al. disclose a bipolar forceps instrument and teach the use of a large number of alternate electrically conductive jaw surface configuration including one wherein the first conductive element (108) comprises first (100a) and second (100b) electrodes extending along the length of the distal portion of the first member and adapted to be positioned adjacent a tissue surface, and the second conductive element comprises a single electrode (102) extending along the length of the distal portion of the second member and adapted

to be positioned adjacent an opposed tissue surface between the first and second electrodes of the first member, see col. 2-5, col. 10, lines 1-36 and figure 9D. Therefore at the time of the invention it would have been obvious to one of ordinary skill in the art to modify the invention of Yamanashi et al. in view of Dorn, as taught by Nezhat et al., to provide an alternate jaw surface configuration wherein the first conductive element comprises first and second electrodes extending along the length of the distal portion of the first member and adapted to be positioned adjacent a tissue surface, and the second conductive element comprises a single electrode extending along the length of the distal portion of the second member and adapted to be positioned adjacent an opposed tissue surface between the first and second electrodes of the first member.

Regarding claim 16, Yamanashi et al. in view of Dorn in still further view of Tetzlaff et al. in further view of Nezhat et al. disclose the claimed invention, see Nezhat et al. figure 9D.

Claim 9 is rejected under 35 U.S.C. 103(a) as being unpatentable over Yamanashi et al. (USPN 5,964,759) in view of Dorn (USPN 6,334,860 B1) in still further view of Tetzlaff et al. (USPN 6,277,117 B1) as applied to claim 1 above, and further in view of Swanson et al. (USPN 6,610,055 B1).

Regarding claim 9, Yamanashi et al. in view of Dorn disclose the claimed invention except for explicitly reciting that at least one of the first and second members is

malleable. Swanson et al. disclose an electrosurgical forceps device and teach that "the forceps-like apparatus 150 includes arms 154 and 156 that are pivotably secured to one another by a pin 158 to allow the device to be opened and closed. The proximal portions of the arms 154 and 156 may be formed from rigid or malleable material. The arm distal portions 160 and 162, which are curved and support the tissue coagulation apparatus 152, are preferably formed from malleable material. This allows the arm distal portions 160 and 162 to be re-shaped by the physician as needed for particular procedures and body structures (note the dash lines in FIG. 21), see col. 16, line 63 through col. 17, line 10 and figures 21-25. Arms 154 and 156 are analogous to the first and second members.

Therefore at the time of the invention it would have been obvious to one of ordinary skill in the art to modify the invention of Yamanashi et al. in view of Dorn, as taught by Swanson et al., to provide the first and second members in a malleable form in order to be re-shaped by the physician as needed for particular procedures and body structures.

Claim 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over Yamanashi et al. (USPN 5,964,759) in view of Dorn (USPN 6,334,860 B1) in still further view of Tetzlaff et al. (USPN 6,277,117 B1) as applied to claim 1 above, and further in view of Chen et al. (USPN 6,102,909).

Regarding claim 12, Yamanashi et al. in view of Dorn in still further view of Tetzlaff et al. disclose the claimed invention except for explicitly reciting that the first and second members are biased in the closed position. It is well known in the art to bias the jaw

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members of forceps in order to hold tissue. Chen et al. disclose an electrosurgical instrument and teach providing the instrument with a means to bias the opposing members in an open or closed position depending on the desired effect, see col. 5, lines 3-6 and col. 16, lines 30-39. Therefore at the time of the invention it would have been obvious to one of ordinary skill in the art to modify the invention of Yamanashi et al. in view of Dorn, as taught by Chen et al., to provide the instrument with a means to bias the opposing members in an open or closed position depending on the desired effect.

Claims 1, 3 and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fozard (USPN 2,888,927) in view of Mehl, Sr. (USPN 5,846,252) in further view of Grisoni (US D452,936 S).

Regarding claim 1, Fozard discloses a medical device (11) comprising a first member (distal portion of first 24 ending in 19) having a first non-destructive tissue-contacting conductive element in communication with a source (10) of ablative energy; and a second member (distal portion of second 24 ending in 18) having a second non-destructive tissue-contacting element, the second member being pivotally coupled (22) to the first member and including a distal tissue-piercing tip adapted to be deployed into tissue to allow the first conductive element to be positioned on a first tissue surface and the second conductive element to be positioned on a second tissue surface opposed to the first tissue surface such that ablative energy can be transmitted between the first and second conductive elements, see col. 1-2 and figure 1. Fozard fails to disclose a second

electrically conductive element on the second member because Fozard discloses a monopolar device. Fozard also fails to disclose that the first and second tissue contacting conductive elements are substantially circular in shape extending along the length thereof. It is extremely well known in the art to bipolar capability to monopolar devices in order to obtain higher localized current densities. Mehl, Sr. discloses a medical device similar to that of Fozard (both are electrical tweezers/forceps devices directed to the removal of hair) and teach the use of a first electrically conductive element (24) disposed on the first member (20) and a second electrically conductive element (26) disposed on the first member (22) in order to provide a bipolar configuration, see col. 3 and figures 1 and 2. It is extremely well known in the art to curved tweezer jaws, wherein the jaws are substantially circular in shape extending along the length thereof. Grisoni discloses are precision tweezers and teaches providing the tweezer jaws in a variety of shapes including curved tweezer jaw shape, wherein the jaws are substantially circular in shape extending along the length thereof. Therefore at the time of the invention it would have been obvious to one of ordinary skill in the art to modify the invention of Fozard, as is well known in the art and taught by Mehl, Sr., to use a first electrically conductive element disposed on the first member and a second electrically conductive element disposed on the second member in order to provide a bipolar configuration, and as is well known in the art and further shown by Grisoni, to provide the tweezer jaws in a variety of shapes including curved tweezer jaw shape, wherein the jaws are substantially circular in shape extending along the length thereof.

Regarding claim 3, Fozard further discloses an actuating member (proximal portions of both 24's) mated to the first and second members and effective to selectively move the members between the open and closed positions, see col. 1-2 and figure 1.

Regarding claim 11, Fozard further discloses that the actuating member comprises opposed first and second handles (proximal portions of both 24's), wherein a force applied to bring the first and second handles in contact with each other causes opening of the first and second members, see col. 1-2 and figure 1.

## Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Aaron Roane whose telephone number is (571) 272-4771. The examiner can normally be reached on 8am - 7pm, Monday - Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda Dvorak can be reached on (571) 272-4764. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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January 24, 2005

hay D. Jelson